International journal of
adulteration

Adulterations of parenteral drugs: Desired health dealt hazard

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To Cite:
Jahangir A, Shah A, Abbas A. Adulterations of parenteral drugs: Desired health dealt hazard. *International journal of adulteration*, 2017; 1: e2ijad3002

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Peer-Review History
Received: 24 August 2017
Reviewed & Revised: 27/August/2017 to 12/October/2017
Accepted: 23 October 2017
Published: 27 October 2017

Peer-Review Model
External peer-review was done through double-blind method.

International journal of adulteration
eISSN (Online) 2456 – 0294

ABSTRACT

Parenteral preparations are those pharmaceutical preparations which are directly released in the blood stream without passing through hepatic metabolism. Any contamination in the preparation has the potential to risk a health hazard to the patient. Since these preparations are more prone to contamination they require critical approaches for maintenance of their integrity. Mal-dispensing practices and poor adherence to storage conditions would contaminate the drug. The drugs act 1976 defines an adulterated drug as one which is either contaminated or by any means injurious to health. Whereas, contaminated drug may lead to serious repercussions such as anaphylactic shock, sepsis, allergic reactions and at times, death. In order to avoid these adverse reactions, acquainted personnel coupled with good manufacturing and dispensing practices are essential which can ensure the integrity of drug from sterile area to the blood stream of the patient thereby avoiding any health promoting or desiring drug to hazard dealing one.

Keywords: Adulteration; Parenteral; Pakistan

1. INTRODUCTION

According to the laws, any factor which is not fulfilling the integrity of preparation will be considered as an adulteration. The Drugs Act 1976 of Pakistan defines a drug to be adulterated if it is not manufactured, packed or held under sanitary conditions, whereby, it has been contaminated with dirt, filth or any other foreign matter or whereby, it may have been rendered injurious to health. (Drug Regulatory Authority of Pakistan, 2014) Since parenteral comes directly in contact with blood stream, they are constrained to be handled critically from their preparation to the blood stream of patient. (Drug Development and delivery, 2014)

Flaws in aseptic control, cross contamination, improper storage and supply (from sterile area to the ward which entails the major factor i.e. temperature, maintenance, etc and above all, the involvement of the unacquainted personnel in the entire system are the major reasons for causing drug contamination and hence adulteration. Following injection of a contaminated drug, complications may occur including anaphylactic shock, sepsis, allergic reactions and at times, death. (Nogler-Semenitz E etal, 2007, Curran E, 2011 and Dolan SA, 2011)

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2. DISCUSSION

A drug is meant to be therapeutically effective but if it is contaminated may not produce the desired therapeutic effect and may harm the patient as well. (Macias AE et al, 2010) As highlighted earlier, the drugs act 1976 marks such drug which become contaminated or injurious to health as an adulterated drug. (Drug Regulatory Authority of Pakistan, 2014) The United States Pharmacopoeia USP stipulated guidelines for parenteral preparations and emphasized the importance of drug stability as injectable drugs are more prone to contamination. (Remigton, 21st Edition) Any lacking in following of defined protocols of parenteral preparation will not only degrade the drug but would lead to serious repercussions. Passing through the primary protective system to the body tissue, parenteral products are regarded as the most delicate preparations. (Meulenhoff PC, 2010) Due to their pharmaceutical issues such as stability problems and direct exposure with the blood stream; they are considered sensitive products which require aseptic condition at all times. (Beany Elison M,)

Out of the manifold reasons of contamination of parenteral preparations poor dispensing practices and poor adherence to the storage conditions poses an array of potential risks of contamination. Furthermore when situation shifts focus on the drug transport, stability of the drug is questioned again. There is a possibility of degradation if drug is carried at unfavourable temperature from pharmacy to the ward, thus affecting drug's integrity. Hence, stability must also be ensured in terms of temperature variation and any physical damage whilst transportation, which may result in contamination. (ASHP guidelines, 2013) Various studies report septic shock, nosocomial and post-surgical infections, anaphylaxis and at times death, following those adulterated injections. (Nogler-Semenitz E etal, 2007, Curran E, 2011 and Dolan SA, 2011)

An adequate quality control and monitoring of the preparation would lessen the untoward reactions' burden, as defined in the USP. (Scott Sutton and David Porter) According to Food and Drug Administration FDA, the Modernized Act 1997 (FDAMA), under the section of 503A, states that the compounded drug will be exempted if it is found adulterated, following good manufacturing practices. (FDAMA, 1997) Parenteral preparation needs a critical approach to ensure its integrity and calls for the expertise of skilled personnel, who are aware of the procedures and protocols especially the good manufacturing and dispensing practices.

3. CONCLUSION

For control of all the aforementioned concerns, acquaint personnel is required to avoid any kind of drug adulteration. Flaw at any stage of preparation may lead to serious consequences. Strict adherence to the good manufacturing practices and quality monitoring deems to be the need of the hour.

CONTRIBUTION OF THE AUTHORS

AJ generated the concept and wrote and introduction, discussion and conclusion with AS. AA supervised the whole assignment, added in the abstract and assisted in the discussion part. AS and AA modified and edited the manuscript. All authors read and approved the final draft.

AJ = Amnah Jahangir, AS = Amna Shah and AA = Atta Abbas

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Ethical issues

Not applicable.

Informed consent

Not applicable.

Funding

This study has not received any external funding.

Conflict of Interest

The author declares that there are no conflicts of interests.

Data and materials availability

All data associated with this study are present in the paper.

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